

**510(K) Summary      JAN 22 1997****Contact Person: Cesar Coral  
President****Date Prepared: September 24, 1996****Trade Name:      SDS Model 1400 XL Deluxe Dental Delivery System****Common Name: Chair Mounted Dental Unit**

The 1400 XL Deluxe Dental Delivery System is designed to conveniently position the dentist's dynamic instruments for use during dental procedures. The arm system the control head is affixed to consists of three pieces. The first section is a rigid arm that mounts on a two inch outside diameter post. Attached to the end of the rigid arm section is a flex arm section that allows for vertical positioning. The flex arm section contains a pneumatic brake that helps provide positive positioning. The third piece is a control mount that allows flexibility in the horizontal positions. The delivery system provides connections for three pneumatically operated instruments. The common instrument used is the dental handpiece. The unit provides automatic instrument selection by means of a three way pneumatic valve located in each instrument hanger assembly. The automatic selection takes place when a static air pressure signal is removed from the top of a diaphragm located in the handpiece control block. The actual activation of the instrument is initiated by pressing on a foot control containing a three way pneumatic valve. The delivery system also provides an air and water syringe for use as the dental procedure may require. The air and water syringe has an autoclavable syringe tip. The control also houses a master on/off control, air volume adjustments for the pneumatic instruments, water coolant volume adjustments, flex arm brake toggle, and an air coolant volume adjustment. There is also a toggle valve located on the control that allows for water purging of the water coolant lines that supply the pneumatic instruments with water coolant. The air and water utilities are supplied through polyurethane tubing housed in a flexible umbilical.

The components that make up this delivery system in many instances are generic to the dental industry and are made of the same materials utilized by other manufacturers that provide an equivalent product. These materials include poly vinyl compounds (PVC), polyurethane tubing, stainless steel, painted steel, anodized and plated alloy compounds, and ABS plastics. These manufacturers would include, but not be limited to, Forest Medical Products, Hillsboro, OR, Beaverstate Dental Inc., Tualatin, OR, Ampco Dental Equipment Company, Santa Maria, CA, and Marus Dental International, Bend, OR.

The delivery system is designed as a dental chair mounted unit and mounts on a two inch steel post. The two inch post is accepted as a dental industry standard. The polyurethane air and water supply lines are connected in a floor mounted metal utility box. The utilities should be provided by contractors, and/or plumbers, that bring the utilities to the required space in compliance with all local codes. The air and water lines have both manual shut off valves and pneumatically controlled automatic shut valves. The pneumatic shut off valves are controlled by the master on/off toggle located on the control section of the delivery system. Also provided in the utility box for both the air and water are filter/regulator assemblies. Recommended air pressure is 80 PSI. Recommended water pressure is 40 PSI.